Nexus Layered Architecture Whitepaper

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Abstract

Sophisticated technology has greatly advanced medical procedures and the level of patient care. However, the advent of new devices and procedures has been somewhat uncoordinated, often leading to clutter in the operating room and increases in the health care providers mental workload. More importantly, this environment can lead to underutilization and improper application of these technologies causing an overall increase in medical errors. To this end, decision, logistic, and process support systems have been developed to marry these systems in an efficient way. They have focused on mitigating single issues such as medication interactions, asset tracking, or medical diagnostics. Commercially available integrated surgical suits are limited to providing central control for medical devices and displaying system status. The key limitation of these systems is that they cannot intelligently monitor processes, make recommendations, inform a team about the status of important processes, facilitate communications and transition of care, and alert them of potential errors. Nexus provides an intelligent human-machine interface comprised of an interface shell, system agents, function agents, a dynamic documentation system, and a layering architecture to improve and coordinate complex clinical processes and technologies. The Nexus system will help to coordinate complex processes in a seamless fashion, while providing timely and intelligent feedback to decrease medical errors.

1 Purpose

Existing information technologies in the medical technology landscape have focused on ameliorating a single issue such as medication interactions [1], asset and personnel tracking, billing, and medical diagnostics [2]. Figure 1 shows the current technology landscape for medical information technologies. Commercially available integrated surgical suits such as STORZ OR1 (patented by Bauer Labs) and CIMIT's OR of the Future are limited to providing central control for medical devices and to displaying clinical and system status information. On the other hand, Nexus technology will integrate and augment these existing technologies and will add the key element of intelligent data analytics so that real time clinical support, error avoidance, documentation, and evidence generation are possible.

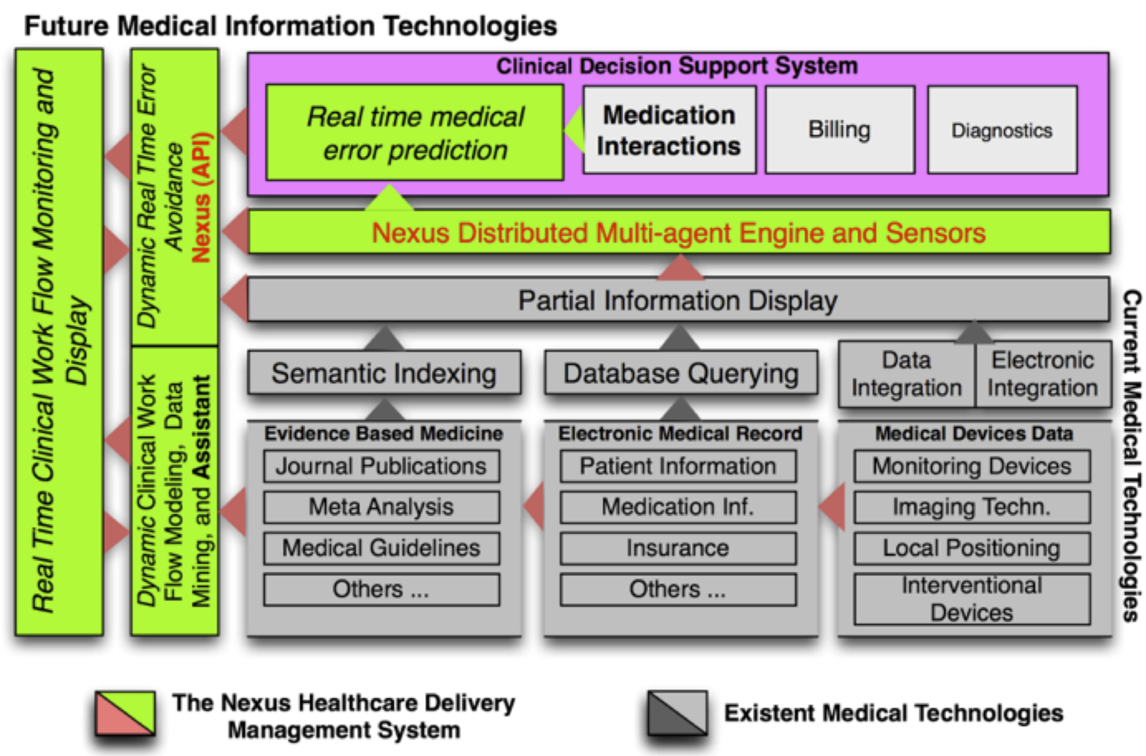

Figure 1: Landscape of future medical information technologies

Definitions:

Real Time Medical Error Prediction

Real time medical error prediction is the ability to estimate the probability of adverse events in real time during a medical intervention. An adverse event could be a deviation from to plan or pathway to a catastrophic failure or the specific process.

Dynamic Clinical Work Flow Modeling, Data Mining, and Assistant
Dynamic clinical work flow modeling is the ability to systematically and interactively capture and link clinical process to identify best-practices that would lead to best outcomes.

Dynamic Real Time Error Avoidance
Dynamic real time error avoidance is the result of integrating real time medical error prediction with real time dynamic clinical work flow modeling to provide intelligent real time medical error avoidance to the clinical team.

Nexus Distribute Multi-Agent Engine
The Nexus DMAE is our proprietary software architecture that enables the integration of historic and real time clinical data sources and the clinical work flow models to provide intelligent real time error avoidance using well engineered human-machine interfaces.

Nexus is a robust, scalable and adaptable software architecture designed to facilitate healthcare processes. It has several novel design aspects: a team-based development methodology, a clear pathway for translating clinical problems to software rules, and modular implementation. It orders chaos but respects fluidity of the clinical environment, provides a strong method for collecting data in an ongoing process while sorting data according to relevance within that process, and provides a portal for staff to participate in process improvement. Existing software architectures cannot accommodate a robust and participant-friendly knowledge model as is possible with Nexus, and therefore the development inputs from other groups are limited and piecemeal. For a new technology to be embraced, it must add value to the provider in terms of real-time decision support, enhancement of situational awareness, logistics coordination, communication support and unburdening of dual documentation. Nexus incorporates dynamic and granular documentation by incorporating temporal and functional tagging of data, which in turn enables intelligent data analytics and knowledge discovery. The Nexus system has been partially implemented and tested for coordinating the initial steps of emergency cesarean delivery; it is aimed at improving situational awareness, anticipating logistical issues, and identifying and correcting potential errors before they adversely affect a patient. Other complex clinical processes such as the coordination of transitions of care for military personnel wounded in the field can be facilitated, improved, and automated by Nexus.

2 Background and Motivation

Since the seminal report by the Institute of Medicine (IOM) in 2000, to Err is Human, marginal reductions in overall medical errors have been achieved; however, there is a need for innovative approaches to understanding and significantly reducing these errors. The IOM report estimates that between 50,000 to 100,000 people die each year due to medical error, costing the US close to $30 billion every year [3]. Decision support systems such as checklists have shown to reduce surgical related errors through an improvement in team communication and coordination [4]. However, these successes have been limited in scope and limited to well understood and narrow clinical problems.

Current information systems cannot intelligently monitor processes, make recommendations, inform the team about the status of important processes, and alert them of potential errors. The closest intelligent systems available are those based on Bayesian models for estimating surgical completion times so that post-operative teams can prepare to receive the patient after surgery [5]. These systems have limited efficacy because they are not fully integrated with other existing technologies such as integrated surgical suites and asset and personnel management systems that provide additional cues for arriving at better estimates of completion time as well as potential logistical, communication, and other errors. Most of the efforts in medical error assessment use retrospective tools implemented after an adverse event has occurred. Tools of this nature including the Root Cause Analysis (RCA) and the Health Failure Modes and Effects Analysis (HFMEA) are limited in their ability to predict future vulnerabilities in the system (latent errors) that could potentially lead to medical errors. However, there are methodologies that have been used in other high-risk complex domains that have the capability to prospectively identify and estimate the likelihood of occurrence of potential failures in the system and processes. One such approach is the Systematic Human Error Reduction and Prediction Approach (SHERPA) that has been widely used and validated in the nuclear power generation industry [6], [7].

3 Nexus Development

We have adapted the SHERPA methodology by including more robust and sophisticated tools that enable the automation of the analysis process and technology. The technology development process began by defining the system and process using the Integration Definition for Function Modeling (IDEF0) technique, which allows the decomposition of a process to the finest level of tasks performed by different parts of the system. Tasks performed by the different members of the clinical team were analyzed using the cognitive task analysis method, which enables the identification of the cognitive abilities used for performing tasks. The next step involved mapping each of the tasks and associated cognitive abilities to a taxonomy of human error that was generated based on an extensive literature review process. The taxonomy describes specific cognitive abilities with their associated limitations that often lead to human error. The final step involved the estimation of the likelihood of occurrence and severity of the identified errors using a group of subject matter and human factor experts. Based on this analysis, the Nexus system displays the prioritized list of most likely and high severity potential failures in a user-friendly fashion, and recommends countermeasures to the clinical team.

To date, the Nexus methodology has been pilot tested and validated for laparoscopic cholecystectomy surgery. The Nexus methodology was able to identify vulnerabilities in the process that were consistent to those in the literature. The Nexus was able to accurately identify critical errors in the surgical process.

As a first implementation of the Nexus we envision the generation of a prioritized list of likely adverse events and possible countermeasure in the form of simple checklist based on the analysis of a process. However, the ultimate solution will be an intelligent and dynamic task management system that provides real time clinical decision support to all members of the clinical team, and has the capability to alert the team if vulnerabilities to human error arise. Along these lines, we have designed and patented an intelligent, layered multi-agent architecture in which key elements of the IDEF0 model team members, equipment, and processes are instantiated as software agents in an integrated hardware/software system to guide, track, and facilitate OR activities (US Patent 7,996,269 B2). Based on initial usability studies of our first two prototypes, the methodology and architecture promise to effectively facilitate critical team clinical processes, such as emergency cesarean delivery (ECD), trauma response, and cardiopulmonary resuscitation. Figure 2 shows Nexus layer architecture.

4 Nexus System Overview

Nexus intelligence is embodied in discrete, dynamic, knowledge-based software objects called Agents, organized in concentric layers: an outer Interface Shell, middle System Agent Mantle, and inner Process Agent Core. The system agents include dynamic, knowledge-based software object sub-agents that model and track the state of a work area. The function agents model, track, and facilitate work area functions. The interface shell provides a hardware and software interface between the system agents and the function agents. The layering architecture comprises a tracking layer, an equipment and supply management layer, a coordination layer, a situational awareness layer, and an oversight layer. The oversight layer combines information from the situational awareness layer with process rule sets contained in the function agents to determine if processes are being performed correctly. The interface processes an integrated collection of facts and relationships and recognizes deviation from or compliance with a predetermined process and communicates this to the user.

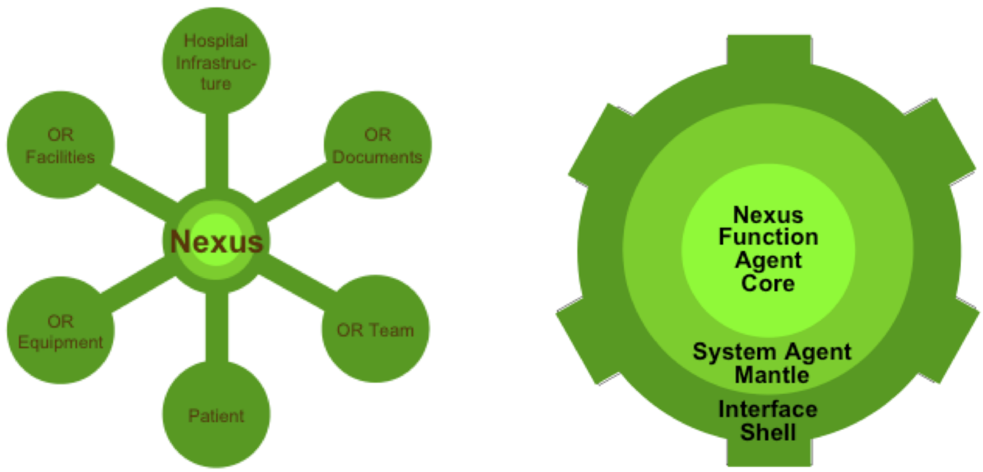

Figure 2: The Nexus architecture

Applying this system to an example in an OR, the Agent objects in the two inner layers comprise a virtual OR consisting of personnel, systems, and processes, which are linked to the real ORs personnel, systems, and processes by its outer layer. The Interface Shell layer consists of hardware and software (host computers, mobile devices, displays, sensors, and effectors) that host the Mantle and Core Agents and link those Agents to the patient, OR personnel, and subsystems. The Shell obtains data from patient, personnel, and subsystems, passes it to Mantle System Agents, and passes information from the Agents back to the personnel and subsystems.

Every person, device, and significant element of the real OR such as the patient, the surgeon, and the electrosurgery unit, even a single sponge can be associated with a System Agent in the Mantle layer. The role of a System Agent is to act as a liaison between real system (via the Interface Shell) and the Core Process Agents. Among other functions, each System Agent maintains a dynamic model of its real system's attributes, state, and behavior, monitors and tracks the state/status of its system, provides system state/status information to other Agents, alerts other Agents and personnel (via their Agents) to non-normal states, and logs relevant time-stamped information from its system to a documentation file.

The Core layer consists of an integrated set of Process Agents, each corresponding to a real OR process. Each Process Agent maintains a model of the real process, including its state of progress; maintains procedural knowledge about the process; monitors OR subsystems relevant to the real process via their System Agents; knows when its process should be initiated; tracks the progress and performance of its process; provides procedural cues to personnel; provides information and decision support; recognizes errors and unsatisfactory process progress or performance and informs personnel; recognizes when its process is completed; and logs significant process events and other information to the documentation file.

An example implementation in an oncology infusion suite is shown in Figure 3. This illustrates the simultaneous lab, clinical, and pharmacy processes that need to operate concurrently for infusion to occur. Nexus can be used to monitor all of these processes in real-time which can help to avoid delays and errors.

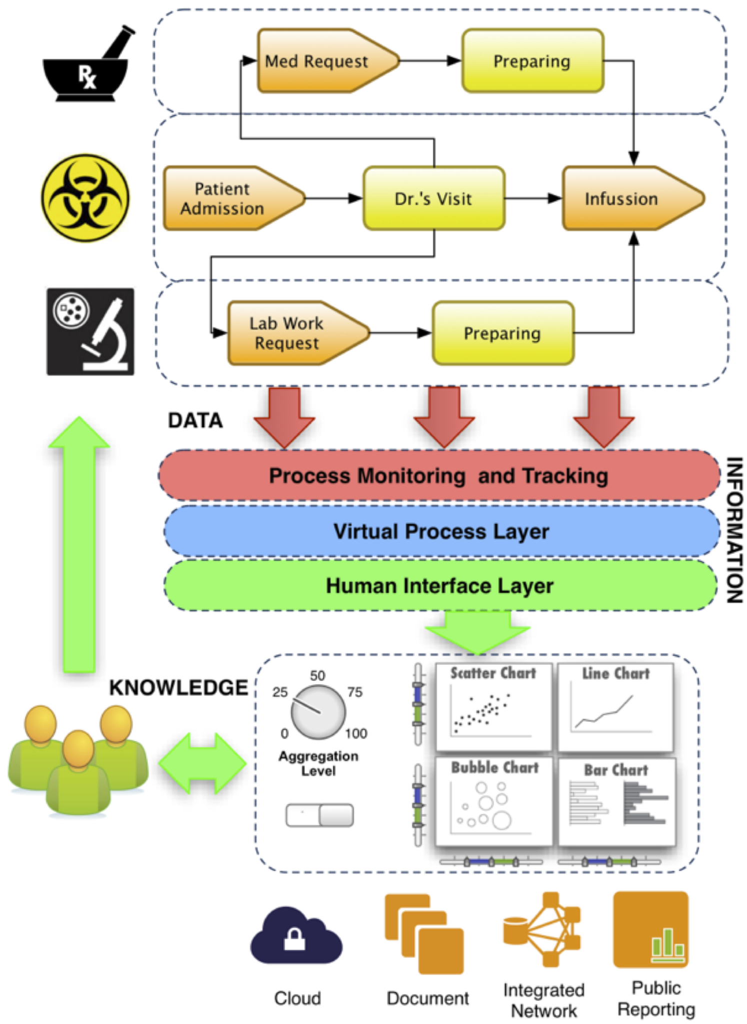

Figure 3: Oncology Infusion Suite Implementation

5 Prior Work

Our current efforts center on the correct and timely execution of emergency cesarean delivery (ECD). In obstetrics, fetal asphyxia and maternal hemorrhage require time critical intervention and often necessitate emergency cesarean delivery to rescue both mother and fetus. The American College of Obstetricians and Gynecologists (ACOG) established that hospitals with obstetric services should have the capability to begin an ECD within 30 minutes of the decision to do so [8]. Hasty preparation for ECD can lead to errors that may compromise safety [9], [10]. For many hospitals, meeting the ACOG 30-minute guideline is a challenge. Even many large urban hospitals with round-the-clock surgical staff and operating rooms reserved for cesarean delivery do not consistently achieve this goal [11]. It is even more daunting for small, rural hospitals [12], where the rate of ECD is higher [13]. Cesarean delivery in rural hospitals also results in a higher rate of anesthesia and infection related complications than in urban settings [14], [15]. Approximately 10% of the increasing number (31% of all deliveries in the USA) of cesarean deliveries are due to emergent conditions [16]. This suggests a growing burden on rural hospitals.

The logistics of rural ECD highlight the problem. If complications develop with an after-hours delivery at a rural hospital and the obstetrician decides that ECD is necessary, many of the required surgical staff are off-site. Commonly, the team must be contacted one at a time by telephone or pager and summoned to surgery. If one cannot be reached or is not available, a call to a backup must be made. The failure to respond to an alert presents a significant problem for hospitals: 30% of pages are never answered, and of those that are, 18% are not attended to within 15 minutes of the initial alert [17]. As the team is arriving at the hospital, the patient must be quickly prepared for surgery. A general purpose operating room (OR) may be the only available facility for ECD, so the present and arriving team members must prepare the OR by collecting equipment that may be dispersed throughout the hospital. The deteriorating condition of patients, the suboptimal state of the OR, the gradual arrival of the team, and the resulting haste, confusion, and anxiety make this system vulnerable to human error. Delays and mistakes can put the mother and child at risk. The Joint Commission reported that in one study involving 47 ECD sentinel events the more significant root causes were communications errors (72 percent), inadequate fetal monitoring (34 percent), unavailable monitoring equipment and/or drugs (30 percent), staffing issues (25 percent), physician unavailable or delayed (19 percent), and unavailability of prenatal information (11 percent) [9]. Furthermore, based on publicly available lawsuit data (http://www.pgh-law.com/cases.htm) delayed ECD is one of the leading obstetric negligence malpractice categories, costing hospitals millions of dollars per year. Rural hospitals need a system to facilitate rapid team assembly and integration, and the quick preparation of patient(s) and

OR for ECDs.

The first prototype, ECDF 0.1, was an electronic storyboard, proof-of-concept system built in Microsoft PowerPoint and Dynamic HTML. The second prototype, ECDF 0.2, was built using Microsoft Access and VisualBasic.Net, and consisted of a local area network, laptop-based server, and tablet computers. ECDF 0.2 was tested in a usability study at PeaceHarbor Hospital in Florence, OR, in which ECD team members evaluated its functionality. Their strong positive comments and constructive criticisms led to the development of ECDF 0.3, a web-based system hosted at Oregon State University. ECDF 0.3 is much more robust, consisting of a MySQL database and PHP scripts that with minor refinements will be suitable for testing in simulated clinical ECD trials. However, ECDF 0.3 requires considerable manual input and its architecture and implementation are very application-specific. It is not suitable for enhancing the functionality needed to provide accurate process tracking, supporting user decision making, or reducing user workload, nor is it readily adaptable to other applications, such as trauma surgery.

6 Future Potential

The next major innovation in the ECDF lies in the implementation. The next prototype, ECDF 0.4, will be an intelligent multi-agent distributed knowledge-based system to monitor real-time team assembly and clinical processes, cue important steps, evaluate process correctness, and alert the clinical team to omissions and errors.

Besides real-time support, Nexus agents in future versions will have the ability to learn best practices (with assistance) and augment existing knowledge so that it can be analyzed and used in subsequent procedures. The collected case documentation could also be stored in a knowledge repository so that learning agents can perform data mining activities that augment the epidemiologic data of the specific procedure and contribute to the generation of evidence based medicine and real time error avoidance.

To realize the full potential of the Nexus technology, Nicolalde R&D, in collaboration with Bauer Labs, is looking for potential partners to assist with the extensive development that is needed to bring this technology to a level where it can be implemented in a wide range of health care settings.

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